



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Cervical Degenerative Disease Treatment

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Cervical Degenerative Disease Treatment*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

On-line submissions: <https://effectivehealthcare.ahrq.gov/get-involved/submit-sead>

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E77D

Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301-427-1496

or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Center (EPC) Program to complete a review of the evidence for *Cervical Degenerative Disease Treatment*. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual

manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Cervical Degenerative Disease Treatment, including those that describe adverse events.

The entire research protocol is available online at:

<https://effectivehealthcare.ahrq.gov/products/cervical-degenerative-disease/protocol>

This is to notify the public that the EPC Program would find the following information on Cervical Degenerative Disease Treatment helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
 - *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions* (KQ)

KQ1. In patients with radiographic spinal cord compression and no cervical spondylotic myelopathy, what are the comparative effectiveness and harms of surgery compared to non-operative treatment or no treatment?

KQ2. In patients with radiographic spinal cord compression and mild to severe myelopathy, what is the effectiveness and harms of surgery versus non-operative

treatment or no treatment? How do the effectiveness and harms vary by level of severity of myelopathy at the time of surgery?

KQ3. In patients with cervical degenerative disease, what are the comparative effectiveness and harms of surgical compared to non-operative treatment?

KQ4. In patients with cervical degenerative disease, what are the comparative effectiveness and harms of therapies added on to surgery (pre- or post-operative) compared with the same surgery alone?

KQ5. In patients with cervical radiculopathy due to cervical degenerative disease, what are the comparative effectiveness and harms of posterior versus anterior surgery?

KQ6. In patients with cervical degenerative disease, what are the comparative effectiveness and harms of posterior versus anterior surgery in patients with greater than or equal to three level disease?

KQ7. In patients with cervical spondylotic myelopathy due to cervical degenerative disease, what are the comparative effectiveness and harms of cervical laminectomy and fusion compared to cervical laminoplasty in patients?

KQ8. In patients with cervical spondylotic radiculopathy or myelopathy at one or two levels, what are the comparative effectiveness and harms of cervical arthroplasty compared to anterior cervical discectomy and fusion?

KQ9. In patients undergoing anterior cervical discectomy and fusion, what are the comparative effectiveness and harms of surgery based on interbody graft material or device type?

KQ10. In patients with pseudarthrosis after prior anterior cervical fusion surgery, what are the comparative effectiveness and harms of posterior approaches compared to revision anterior arthrodesis?

KQ11. In patients with cervical spondylotic myelopathy, what is the prognostic utility of preoperative magnetic resonance imaging (MRI) findings for neurologic recovery after surgery?

KQ12. What is the sensitivity and specificity of imaging assessment for identifying symptomatic pseudarthrosis after prior cervical fusion surgery?

KQ13. In patients with cervical spondylotic myelopathy, what are the comparative effectiveness and harms of intraoperative neuromonitoring (e.g., with somatosensory or motor evoked potential measurements) versus no neuromonitoring on clinical outcomes in patients undergoing surgery?

*For purposes of these key questions, we are focusing on symptomatic cervical degenerative disc disease; with the exception of Key Question 1, evaluation and management of asymptomatic disease is beyond the scope of this review.

Contextual Questions (CQ)

CQ1. What is the prevalence of cervical degenerative disease with spinal cord compression in asymptomatic patients?

CQ2. What is the natural history of untreated spinal cord compression in patients with cervical degenerative disease?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

	Inclusion	Exclusion
--	------------------	------------------

Population	<ul style="list-style-type: none"> • Age 18 and above with symptomatic cervical degenerative disease (e.g., pain, radiculopathy, myelopathy) for all KQs except for KQ1, which includes asymptomatic patients • Effectiveness and harms of surgery based on patient characteristics, disease characteristics and radiographic characteristics (e.g., age, gender, comorbidities [e.g., comorbid lumbar disease, autoimmune disease, neurological disease, mental illness, Down's syndrome], severity of cervical degenerative disease, Frailty Index, sagittal vertical aspect, degree of kyphosis, prior treatment [e.g., bracing, traction, medications, massage, acupuncture, injections, chiropractic care, spinal manipulation], duration of pain, skill of surgeon) 	<ul style="list-style-type: none"> • Younger than 18 years • Patients without cervical degenerative disease • Nonhumans
Intervention	<ul style="list-style-type: none"> • Cervical spine surgery (e.g., discectomy, disc replacement, fusion, arthroplasty, laminectomy, laminoplasty, corpectomy, cervical hybrid surgery, foraminotomy) • Non-surgical treatments (e.g., heat, exercise, acupuncture, drugs, radiofrequency ablation, steroid injections, Botox® for neck pain, psychological strategies [e.g., cognitive behavioral therapy], occupational therapy, multidisciplinary rehabilitation) • Intraoperative neuromonitoring • Imaging to identify symptomatic pseudarthrosis after cervical fusion surgery • Preoperative MRI to predict neurologic recovery in myelopathy 	<ul style="list-style-type: none"> • Preoperative imaging using CT or plain films
Comparators	<ul style="list-style-type: none"> • Any included intervention • Placebo, waitlist, active control 	<ul style="list-style-type: none"> • Nonoperative intervention versus nonoperative intervention without surgical comparator
Outcomes	<ul style="list-style-type: none"> • Pain, sensory function, motor function, gait, quality of life (e.g., VAS, NRS, NDI, SF-36, SF-12, EQ-5Dm, mJOA score, Nurick score, MDI, PROMIS-29, dysphagia scales, return to work) • Fusion rate, reoperation rate • Harms (e.g., withdrawals due to adverse events, serious adverse events, new 	<ul style="list-style-type: none"> • Nonvalidated instruments

	symptomatic adjacent segment disease, postoperative infection, device failure, ossification of the posterior ligament, development of kyphotic deformity) • Sensitivity and specificity of imaging after cervical fusion surgery	
Timing	• All time periods	
Setting	• Inpatient, outpatient, ambulatory surgical centers	
Study Design	• RCTs, prospective trials and retrospective observational studies with a control group (study N \geq 50), current systematic reviews for identification of additional studies	• Pre-post single-arm studies, case series, case reports, systematic reviews published prior to 2007

CT = computed tomography; EQ-5D = EuroQol-5 dimension instrument; KQ = key question; MDI = myelopathy disability index; MRI = magnetic resonance imaging; mJOA = modified Japanese orthopedic association scale; NDI = neck disability index; NRS = numerical pain rating scale; PROMIS-29 = patient reported outcome measurement information system; RCT = randomized controlled trial; QOL = quality of life; SF = short form health survey (12 or 36 items); VAS = visual analogue scale for pain.

Dated: August 9, 2022.

Marquita Cullom,

Associate Director.

[FR Doc. 2022-17371 Filed: 8/11/2022 8:45 am; Publication Date: 8/12/2022]